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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,467	03/05/2004	Richard F. Wenstrom JR.	MIT5027USNP	2466

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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11/16/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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gsanche@its.jnj.com

Office Action Summary	Application No. 10/708,467	Applicant(s) WENSTROM ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-18,34,35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-18,34,35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on 08/24/2010, PROSECUTION IS HEREBY REOPENED. Rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Objections

Claim 9 is objected to because of the following informalities: Claim 9 would be clearer if "a cutting edge" was changed to "the cutting edge," since the claim feature "cutting edge" is already recited in preceding claims, e.g. independent claim 1, line 4. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-18 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from claim 1, line 5, whether the claim requires that the “cutting element” be “spaced away from and not normal to the elongate member,” or whether the claim requires that the “cutting edge” be “spaced away from and not normal to the elongate member.” For examination purposes, the claims will be considered as requiring that the cutting edge be spaced away from and not normal to the elongate member.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

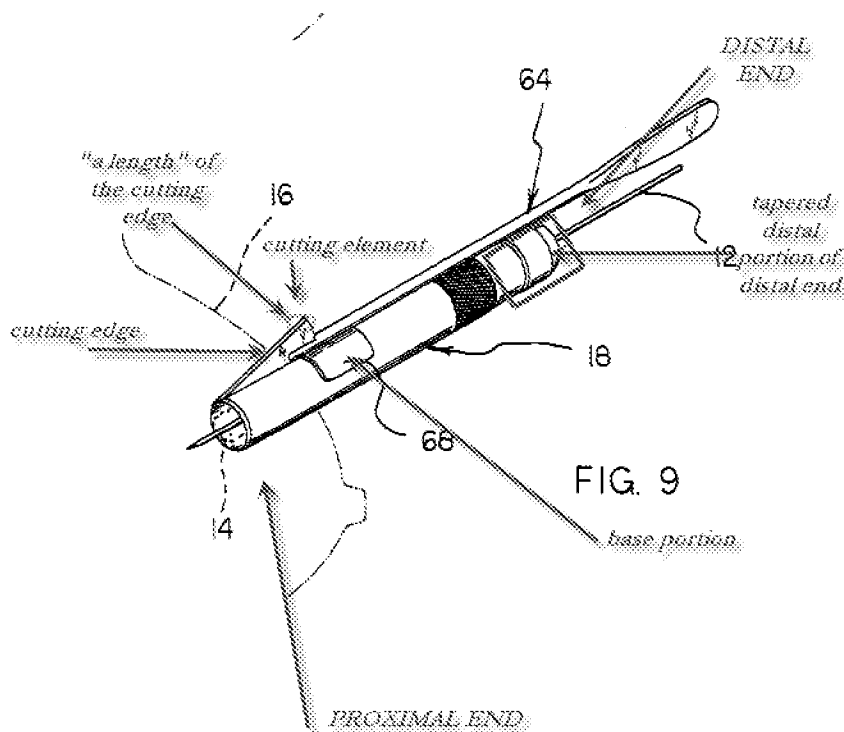
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9, 11-13, 34-35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Russin (U.S. 5,807,276).

Russin discloses a tunnel notcher and guidewire delivery device, comprising an elongate member with proximal and distal ends (see marked-up figure below) and an

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inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire (ref. #12); and a cutting element (ref. #72) disposed proximal to the distal end of the elongate member and adapted to remove bone, i.e. capable of removing bone, within an opening of a bone tunnel, the cutting element being substantially wedge-shaped and extending radially outward from the elongate member. The cutting edge (see marked up figure) is spaced away from the elongate member (when ref. #68 is advanced to the proximal end, not illustrated) and extends not normal to the angle member.



A distal portion of the distal end of the elongate member is substantially tapered (ref. #22, sharpened edge). The cutting element is disposed proximal to the substantially tapered distal portion of the elongate member. The cutting element

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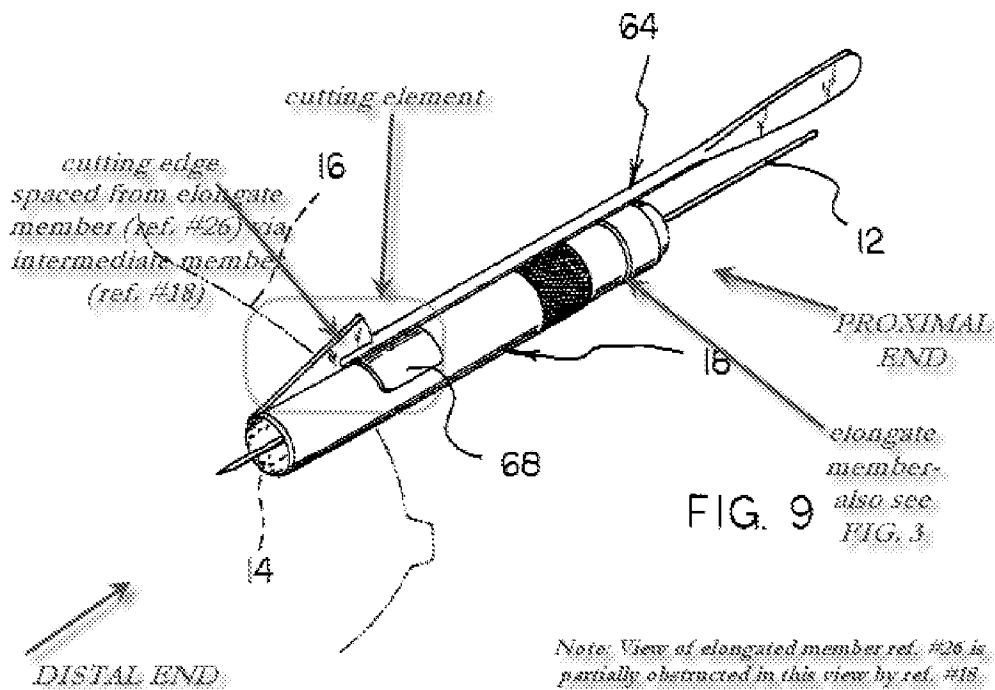
includes a base portion (ref. #68) coupled to the elongate member and the cutting edge positioned a distance apart from the elongate member.

The cutting edge has “a length” less than the diameter of the elongate member (see marked-up figure). The cutting element is adapted to create a notch in bone having a substantially semi-circular shape.

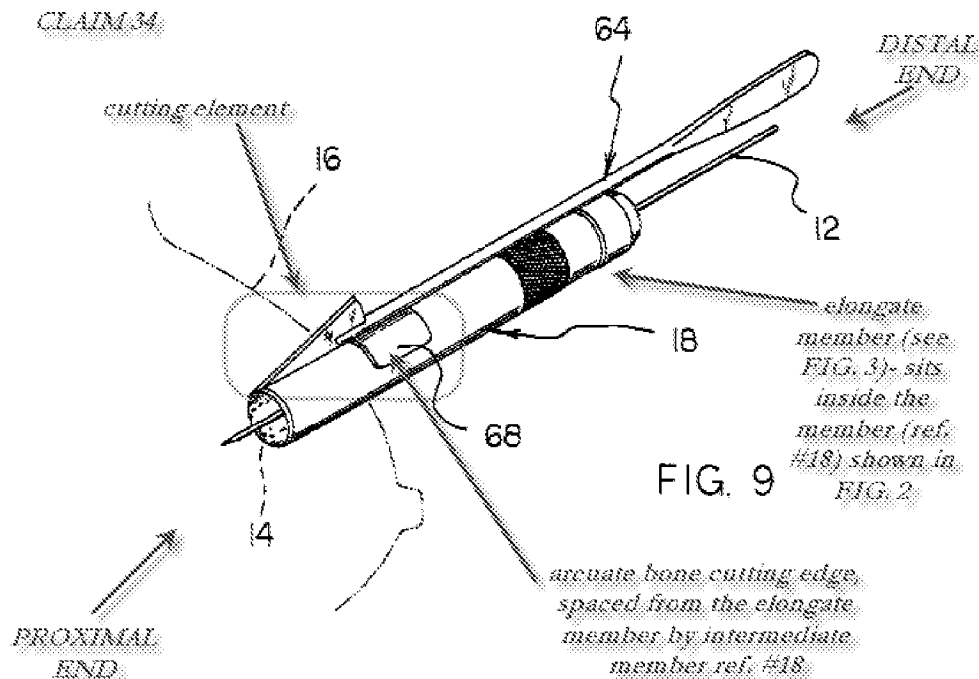
The device further comprising a plurality of indicia (shown at ref. #36 in FIG. 1) formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a bone tunnel.

The distal portion has a length greater than “a length” of the cutting element (ref. #72).

According to another interpretation, Russin discloses a device comprising an elongate member (ref. #26, FIG. 3) with proximal and distal ends and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire (ref. #12); and a cutting element (ref. #70) having a distal bone cutting edge disposed proximal to a distal portion of the elongate member (when the cutting element is first advanced along the device, *i.e.* prior to the orientation shown in Fig. 9), and being spaced away from the elongate member (via ref. #18, FIG. 2), the cutting element being adapted to remove bone within an opening of a bone tunnel, the cutting element being the only cutting element disposed on the elongate member and being substantially wedge-shaped and extending radially outward from the elongate member.



Regarding claim 34, Russin discloses a device (see next marked-up figure) comprising an elongate member (FIG. 3) with proximal and distal ends and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire (ref. #12); and a single cutting element (ref. #'s 68 and 70) disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being the only cutting element disposed on the elongate member and being substantially wedge-shaped (at ref. #70) and extending radially outward from the elongate member and having a bone cutting edge (front edge of ref. #68) that has a substantially arcuate shape spaced apart from and circumferentially oriented with respect to the elongate member.

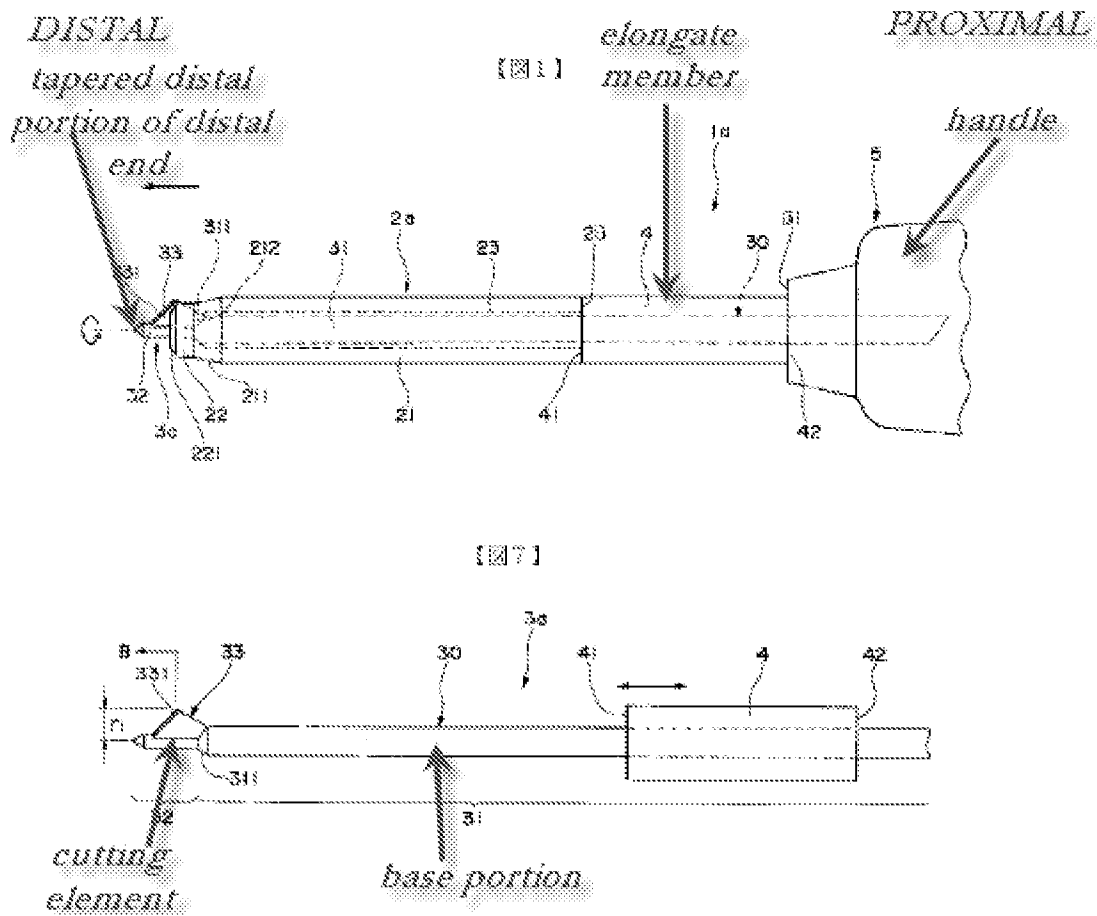


Claims 1-3, 9-12, 14-15, 35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama Hitoshi (JP 9149907).

Akiyama Hitoshi discloses a tunnel notcher and guidewire delivery device, comprising: an elongate member (ref. #4) with proximal (right) and distal ends (left) and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire; and a cutting element (ref. #33) having a distal bone cutting edge disposed proximal to a distal portion of the elongate member (when the cutting element is being advanced from the right to left, not illustrated), and being spaced away from and not normal to the elongate member, the cutting element being adapted to remove, *i.e.* capable of removing, bone within an opening of a bone tunnel, the cutting element

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being the only cutting element disposed on the elongate member and being substantially wedge-shaped and extending radially outward from the elongate member.



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The cutting edge that is positioned a distance apart from the elongate member has “a length” that is less than a diameter of the elongate member.

The cutting element is adapted to create a notch in bone having a substantially semi-circular shape.

The device further comprises a handle (ref. #5) disposed on a proximal portion of the elongate member. The handle extends in a direction transverse to a longitudinal axis of the elongate member.

The width of the cutting element increases in a proximal to distal direction.

The distal portion of the elongate member has “a length” greater than a length of the cutting element.

Response to Arguments

Applicant's arguments with respect to claims rejected 35 U.S. 112, 1st, have been considered and are persuasive.

Applicant's arguments filed 08/24/2010 have been fully considered but they are not persuasive.

Applicant argues that the device of Russin differs from the invention because Russin lacks a bone cutting edge spaced away from the elongated member, and also because Russin is not adapted for removing bone.

As discussed above, the cutting edge is spaced away or positioned a distance apart from the elongate member when ref. #68 is advanced to the proximal end of elongate member ref. #18, not illustrated. Also, in another interpretation of the

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reference, the cutting edge is spaced away from the elongate member ref. #26 via intermediate member ref. #18.

In response to applicant's argument that the device is intended for cutting soft tissue and not for cutting a semi-circular notch in bone, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the cutting edge would be capable of cutting notches of any shape in bone, especially diseased bone, spongy bone, or smaller bones.

With regard to the recitation "a length," it is noted that "a length" does not necessary refer to an entire length or total length of a member, but merely a length, *i.e.* any arbitrary length on the member.

For the foregoing reasons, the rejection is deemed proper.

Conclusion

Applicant's amendment filed 09/10/2009 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733